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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,261	08/27/2003	Raymond Kim	20144-003100US	6593

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EXAMINER

HINES, JANA A

ART UNIT PAPER NUMBER

1645

DATE MAILED: 06/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/650,261	Applicant(s) KIM, RAYMOND	
	Examiner Ja-Na Hines	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment Entry

1. The amendment filed March 29, 2006 has been entered. Claims 1-13 and 26 have been cancelled. Claim 21 has been amended. Claims 14-25 are under consideration in this office action.

Withdrawal of Objections and Rejections

2. The following objections and rejections have been withdrawn in view of applicants' amendments and arguments:

- a) The objection of claim 26 to under 37 CFR 1.75(c);
- b) The rejection of claim 21 under 35 U.S.C. 112, second paragraph; and
- c) The rejection of claim 26 under 35 U.S.C. 103(a) as being unpatentable over Greenquist (US Patent 4,806,312 published February 21, 1989) in view of Nelson et al., (1995. Ana. Chem).

Response to Arguments

3. Applicant's arguments filed March 29, 2006 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. The rejection of claims 14-22 and 25 under 35 U.S.C. 102(b) as being anticipated by Greenquist (US Patent 4,806,312 published February 21, 1989) is maintained for reasons already of record.

The rejection was on the grounds that Greenquist teaches an apparatus comprising a molecular analyte layer and a film layer wherein the molecular analyte layer comprises a molecular analyte immobilized on a molecular analyte solid support, wherein said molecular analyte comprises a molecular ligand binding site; and (ii) the film layer comprises a molecular ligand zone having a molecular ligand, wherein, upon wetting of the molecular ligand zone, the molecular ligand can diffusibly migrate to the molecular ligand binding site of the molecular analyte to produce a detectable product. Applicants' argue that Greenquist's labeled reagent is permitted to diffuse into the detection layer since only the labeled reagent/analyte complex is allowed to migrate. However it is the examiner's position that the labeled form of a binding partner of the analyte is equivalent to the molecular ligand found on the film layer (reagent layer). Therefore, the label itself was not being set forth as the molecular ligand, but the labeled form of the binding partner. The analyte can be a peptide, protein nucleic acid or other molecule for which a specific binding partner or counterpart exist (col. 17, lines 30-36). It is noted, that the terms molecular analyte and molecular ligand are interchangeable with the terms labeled reagent and detection reagent used by Greenquist, since both pairs refer to binding partners and their counterparts. Thus, applicants' argument is not persuasive.

Applicants' urge that the molecular ligand does not encompass the labeled reagent/analyte complex. However it is the examiner's position that the instant specification does not prevent the labeled reagent/analyte complex from being embraced by the definition of molecular ligand. The specification on page 4 states that "Molecular ligand" as used herein means any non-whole cell compound or molecule of interest for which a diagnostic test is desired. A molecular ligand can be, for example, a protein, peptide, carbohydrate, polysaccharide, glycoprotein, hormone, receptor, antigen, antibody, substrate, metabolite, transition state analog, cofactor, inhibitor, drug, dye, nutrient, growth factor, *etc*, without limitation. Thus, not only does the molecular analyte meet the definition, the labeled reagent/analyte complex is a non-whole cell complex and also a molecule of interest for which a diagnostic test is desired, hence the reason it is labeled and detected. Therefore applicants' arguments are not persuasive and the teaching of Greenquist meets the definition set forth by the specification contrary to applicants' statements.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The rejection of claims 23-24 under 35 U.S.C. 103(a) as being unpatentable over Greenquist in view of Bergstrom et al., is maintained for reasons already of record. The

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rejection was on the grounds that no more than routine skill would have been required to modify the apparatus of Greenquist to incorporate hydrogel which is comprised of agarose as taught by Bergstrom et al., since the art already teaches that the layers of the apparatus may be of matrix forming agarose materials.

Applicants' assert that all of the elements of the claims have not been taught. Furthermore, in response to applicant's arguments against the Greenquist reference individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, the rejection was over a combination of references, however the arguments only concentrate on the teaching of Greenquist. Therefore, it is the examiner's position that Greenquist has been discussed above and only routine skill would have been required to incorporate hydrogel, since the art already teaches the advantages of hydrogel and matrix forming agarose materials. Thus applicants' arguments about the properties of the labeled reagent are misplaced, since the molecular ligand refers not to the label but to the binding partner. There is no limitation on the number of binding sites on the binding partner.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in

the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, no more than routine skill would have been required in using a well known alternative and functionally equivalent material hydrogel when other matrix forming materials are known in the art to be essential for obtaining a sensing surface and is desirable for aiding protein compatibility and minimizing nonspecific interactions.

Applicants' urge that there is expectation of success. However it is the examiner's position that the expectation of some advantages is the strongest rationale for combining references. The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. *In re Sernaker*, 702 F.2d 989, 994-95, 217 USPQ 1, 5-6 (Fed. Cir. 1983). See M.P.E.P 2144. However, contrary to applicants' assertions, one of ordinary skill in the art would have a reasonable expectation of success because no more than routine skill would have been required to use a known member of a class of materials such as hydrogel in a apparatus since other members of matrix forming materials comprised of agarose were known to be useful for the purpose of forming layers within the apparatus.

Conclusion

6. No claims allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
June 7, 2006



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